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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,448	05/03/2001	Ismat Ullah	TN1A CIP	3068

7590 08/23/2005

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/848,448	ULLAH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,8-16,18,20-24,27-31,54 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,8-16,18,20-24,27-31,54 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 04/11/05.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 8-24, 27-31, 54 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "said enteric coating excluding hydroxypropylmethyl cellulose phthalate" in claims 5 and 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 8-24, 27-31, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 5,225,202), in view of Tanaka et al. US 5,109,003.

Hodges teaches coated pellets composition comprising drug-containing core, and an enteric coating layer surrounding the core, wherein the enteric coating will provide protection of the medicament at pH less than 3, but will allow for drug release at a pH of 4.5 or higher (see abstract; column 2, lines 35-53; and column 3, lines 10-15). Drug in the core is an acid labile drug includes dideoxyinosine (ddI) (column 3, lines 16-19). The core further comprising one or more disintegrants such as sodium starch glycolate, corn starch, or cross-linked polyvinylpyrrolidone in an amount of from about 2 to about 15%; and binder in an amount of from 0 to about 20% (column 3, lines 20-26, 54-64). The enteric coating layer comprising hydroxypropylmethylcellulose phthalate (HPMCP); plasticizer such as diethyl phthalate, triethyl citrate, or polyethylene glycol; and anti-adherent such as talc, magnesium stearate, or fumed silica (column 4, lines 17-51). The coated pellets may be filled into hard shell capsule (column 6, lines 3-4). Hodges further teaches the use of buffering agent in the core, as well as in the enteric coating layer, such as sodium hydroxide (see abstract, column 3, lines 5-10, and column 4, lines 38-39). Hodges also teaches the subcoat layer between the core and outer enteric coating layer. However, Hodges discloses that the subcoat layer *may* be needed only where the core includes a drug which is incompatible with the enteric

coating layer (column 4, lines 59-65). It is noted that all of Hodges' examples that include the subcoat layer show the use of pravastatin as the active agent. None of the examples show subcoat layer used in ddI composition.

Hodges does not explicitly teach the amounts of the ingredients, as well as sodium carboxymethylcellulose as a binder, and methacrylic acid being the enteric coating polymer. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Regarding sodium carboxymethylcellulose, and methacrylic acid copolymers, it is the position of the examiner that sodium carboxymethylcellulose is a well known binder, and methacrylic acid copolymer is a well known enteric coating copolymer. However, to be more specific, Tanaka is cited, wherein Tanaka teaches an enteric coating composition comprising binder such as sodium carboxymethylcellulose, and enteric coating polymer includes HPMCP or methacrylic acid copolymers (column 5, lines 46-64). Thus, it would have been obvious for one of ordinary skill in the art to modify the coated pellets composition of Hodges using sodium carboxymethylcellulose as the binder, and methacrylic acid copolymers as the enteric coating polymer in view of the teaching of Tanaka, because Tanaka teaches an enteric coating composition comprising a well known binder and a well known enteric coating polymer such as HPMCP and methacrylic acid copolymers, and because Hodges teaches an enteric

coated pellets composition that has good resistance to deterioration at pH less than 3 but have good drug release properties at greater than 3.

Response to Arguments

Applicant's arguments filed 04/11/05 have been fully considered but they are not persuasive.

On page 6, paragraph 8, of the Remarks filed 04/11/05, applicant states that:

> During a telephone discussion with the Examiner on December 30, 2004, the Examiner indicated that the subject application could possibly be allowable over USPN 5,225,202 (Hodges et al.) if applicant agreed to amend the claims to delete hydroxypropylmethyl cellulose phthalate.

The examiner would like to state for the record that this statement is not consistent with the recollection of the examiner. Hydroxypropylmethyl cellulose phthalate was recited in the dependent claim, and the deletion of such would not place the application in condition for allowance. Moreover, Takada et al., the secondary reference, teaches an enteric coating includes hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, polyvinyl alcohol phthalate, methyl methacrylate, methacrylic acid copolymer, and methyl acrylatemethacrylic acid copolymer (column 5, lines 58-66). Thus, it would have been obvious for one of ordinary skill in the art to modify the enteric coating of Hodges using methyl methacrylate, methacrylic acid copolymer, and methyl acrylatemethacrylic acid copolymer, because Takada recognizes the equivalency of the enteric coating polymer including hydroxypropylmethyl cellulose and the methacrylic acid copolymer.

Applicant argues that ddI is incompatible with enteric coating layer, therefore, Hodges will have to employ a subcoat layer. Contrary to the applicant's argument, Hodges teaches the use of buffering agent in the core, as well as in the enteric coating layer to prevent drug degradation due to acid in the low pH environment (see abstract, column 3, lines 5-10, and column 4, lines 38-39). Nowhere in Hodges is the disclosure of ddI-containing core having a subcoating layer found. It is noted that only pravastatin-containing core has the subcoating layer (see all examples).

Applicant argues that in view of the differences, which differs are unobvious, it is submitted the instant application is patenable over Hodges et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that applicants' claims are directed enteric-coated beadlets and not an enteric-coated tablet or granule as disclosed by Tanaka; and the enteric-coated beadlets include ddI and not an ulcer drug as in Tanaka. Thus, it is seen that the very nature and inventive concept of Tanaka is totally different from applicant's composition as claimed. Thus, it is submitted that applicant's composition as claimed is patentable over Tanaka. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231

USPQ 375 (Fed. Cir. 1986). Tanaka is cited as a secondary reference in combination with Hodges. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Tanaka is cited solely fro the teaching of binder such as sodium carboxymethylcellulose, and enteric coating polymer includes HPMCP or methacrylic acid copolymers (column 5, lines 46-64).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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